IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Plaintiffs' Response to Order

"Given the significant number of people who will be affected by this matter," ECF No. 109 at 2, Plaintiffs requested that the Court enter final judgment so that an appeal may proceed expeditiously, and Plaintiffs' litigation opponents joined that request. *See* ECF No. 108. Plaintiffs sought entry of final judgment *against themselves* to obtain timely relief following the Court's denial of their motion for a preliminary injunction. The Court's subsequent denial of the Food and Drug Administration's motion to stay summary-judgment proceedings and stated intention to issue a final judgment "by the end of April," ECF No. 106 at 2, mean that Plaintiffs' preliminary-injunction appeal will be mooted before it can be decided, *see Koppula v. Jaddou*, 72 F.4th 83, 84 (5th Cir. 2023), and left Plaintiffs little choice but to withdraw their motion seeking to expedite that appeal, CA5 Dkt. No 41. Meanwhile, the FDA refuses to extend its prior enforcement discretion policies during either summary-judgment or appellate proceedings. Thus, pharmacy compounding of "essential copies" of FDA-approved tirzepatide products became prohibited on March 6, and bulk tirzepatide compounding by outsourcing facilities became prohibited on March 19. Right now, the significant number of people who depended on compounded products for years cannot get them, and Plaintiffs have no obvious course to obtain timely relief that restores patient access and remedies their injuries. Unless the Court determines that summary-judgment proceedings involving the same issues and arguments have value because they might lead the Court to reach a different outcome, it should proceed as the parties jointly requested so that Plaintiffs may seek to vindicate their position expeditiously in the Fifth Circuit.

The Court ordered the parties to "submit … any excerpts of the administrative record they wish the Court to see prior to the entry of a judgment on the merits." ECF No. 109 at 2. Plaintiffs addressed record excerpts in their reply brief. *See* ECF No. 98 at 1, 4–9; ECF No. 98-1. To satisfy the Court's order, and to ensure a full record, Plaintiffs now file additional pages to provide context to those pages already presented, FDA251–58; FDA286–89; FDA303–06; FDA334–35; FDA350–58; FDA410–17; FDA422-37; FDA453–56; FDA459–92; FDA570–79. Additionally, Plaintiffs presented with their opening preliminary-injunction filing documents they understood to have been provided to FDA, and they now file certain documents FDA refers to as "Other Records" to

confirm the scope of the administrative record concerning such materials. FDA000607–1018; 1422–1606. *See* ECF No. 76 at 1, 3. In addition, in response to the Court's representation that it "does not wish to give (or even appear to give) short shrift to the Parties' arguments and positions," Plaintiffs provide a brief description of the significance of key record excerpts to explain what "they wish the Court to see."[1] ECF No. 109 at 2.

1. There can be no question that FDA acted arbitrarily and capriciously in initially resolving the tirzepatide shortage in October 2024. The record proves FDA knew zero about the ability of Eli Lilly and Company (Lilly) to meet demand: it did not know what the supply was, or what the demand was, for any time period. Leading into the October decision, [redacted] —until two weeks *after* this Court remanded the matter pursuant to *this lawsuit*.[2] FDA415–17. FDA proved itself more than willing to "blindly rely on Lilly's assertions." ECF No. 100 at 24 n.12. That willingness did not suddenly abate before FDA's December final action (the Decision) when it—no surprise—reached the same outcome as in October.

2. There can be no question that FDA did not analyze Lilly's evidence concerning supply and demand for a settled "period of time." ECF No. 100 at 18. Lilly explicitly told FDA [redacted] The statutory mandate went unmet.

Why does that matter? In practical terms, it is because the most basic way to discern whether accounting representations may be flawed—e.g., infected by anything ranging from

[1] Because Lilly and FDA did not openly proclaim on the record that there is an ongoing shortage, the Court should not expect "to see" proof of shortage without some explanation of the record materials in question. If that is beyond what the Court intended, the Court should ignore the remainder of this filing.

[redacted]

inadvertent mistake to outright fraud, or simply not representing what the reader assumes they do—is to see if numbers across statements *match* each other. For instance, if a mortgage lender received a purported bank statement and a purported wage statement from the same mortgage applicant, and those documents showed *different* figures representing the applicant's payable wages, the mortgage lender would obviously be dissatisfied. If the applicant responded that the discrepancy arose from the fact that the two statements reflect different time periods, the lender would demand documentation aligning the figures by *the same* time period to make sure they match. If that did not happen, the lender would deny the application and may even refer the matter for investigation. To do anything else would be to "blindly rely on … assertions" that are at least questionable (or worse). ECF No. 100 at 24 n.12.

Here, the record shows that FDA noticed what Plaintiffs noticed: [redacted] FDA476. Plaintiffs noticed this without the benefit of the administrative record, *see* ECF No. 65 at 17, and repeated the point after receiving the administrative record, *see* ECF No. 98 at 6. (The Court's order did not address this point.) When FDA made its inquiry about this discrepancy, Lilly provided two responses. One was [redacted] That record item answers the Court's near-exclusive reliance on Lilly's cumulative figures in ratifying FDA's belief that Lilly could meet orders over a 15-month time period. *See* ECF No. 100 at 19–28.

Lilly's second response was (as quoted above) that [redacted] But rather than request [redacted]

[redacted] FDA was content to issue a decision with numbers that simply do not add up—by Lilly's admission. To ask that an agency ensure that numbers in its decision-making add up is not to demand that the agency "be perfect." ECF No. 100 at 21; *cf. Nat'l Treasury Emps. Union v. Fed. Lab. Rels. Auth.*, 942 F.3d 1154, 1157 (D.C. Cir. 2019) (action is arbitrary if it "is mathematically false").[4]

3. The record supports Plaintiffs' showings that the numbers FDA relied upon in the Decision are internally conflicted. To begin, Plaintiffs did not inflexibly insist that "the FDA should have considered the data on a month-to-month basis." ECF No. 100 at 22; *see* ECF No. 98 at 7 (calling for "a set time period" such as "months or quarters"). Plaintiffs ran monthly calculations for two reasons—one legal and one practical. The legal reason is that FDA's shortage listings must be "up-to-date." ECF No. 100 at 8. While different time periods might work—e.g., daily, weekly, monthly, and perhaps quarterly assessments—a running cumulative total well over one year is not an up-to-date assessment. *Compare id.* at 10–11 (describing what up-to-date determination might look like) *with id.* at 18–19 (excusing FDA from anything like that type of determination).

The practical reason is that [redacted]; ECF No. 98 at 5; ECF No. 65 at 16. Likewise, [redacted].[5] *See, e.g.*, ECF No. 65 at 17 and n.10; *see*

[4] This and similar authority answer the Court's belief that FDA's decision can stand even if its finding of monthly demand "is unsupportable." ECF No. 100 at 24. Arbitrary-and-capricious review is not so "toothless." *Louisiana v. United States Dep't of Energy*, 90 F.4th 461, 470 (5th Cir. 2024) (citation omitted).

[5] To be sure, this mode of comparison is limited by Lilly's failure [redacted] That failure only counts against FDA's and Lilly's position.

also FDA436. A monthly baseline therefore provides a feasible means of checking whether Lilly's figures are internally consistent and ultimately a suitable basis for evaluation of shortage.

4. The record demonstrates that FDA's determination that the shortage was resolved relies on data that contradict the FDA's decision. One pertinent example is [redacted] This was literally a period of time where supply fell below demand. And it was the most up-to-date evidence leading into FDA's decision. How can an agency maintaining "up-to-date" shortage list rationally ignore that the same data it relied upon shows the drug in question to be in shortage? Neither the Court's order nor any brief of the Defendants has an answer. Nor could the agency provide one now. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943).

[redacted]

5. The trove of evidence showing that pharmacies cannot order tirzepatide products from wholesalers confirms a shortage. FDA000607–1606. It is not correct to construe the record to support FDA's belief that this evidence reflects localized shortages inevitably resolved in "a day or two." ECF No. 100 at 25. The record shows pervasive, nationwide delays that are substantial. Among other things, the record includes more than 100 pages of screen shots showing that pharmacies had limited or no supply of brand-name tirzepatide products. *See* FDA679–693; FDA710–713; FDA849–853; FDA857–60; FDA982–1017; FDA1521–1584; FDA1590–1606.

[redacted]

FDA1450 (emphasis added); *see also* FDA1438–40; FDA1450; FDA1451; FDA1485; FDA1529–1531; FDA1541–1542; FDA1544; FDA1576.

[redacted] FDA1451 (emphasis added). This refutes the notion that pharmacies could receive brand-name tirzepatide products within a few days: [redacted] [redacted], this evidence refutes the notion that supply disruptions were "localized" rather than national. *See* ECF No. 100 at 66. This evidence also contradicts Lilly's representations of wholesalers' stock: if those representations were true, wholesalers would have had the stock.

The record also contains cover notes identifying the screen shots and providing information like dates. *See, e.g.*, FDA677; FDA677–93; FDA846–47; FDA854–56; FDA861–62. These show that the screenshots were predominantly taken [redacted] and thus represent the most up-to-date information available as of the December 19, 2024, agency action. *See, e.g.*, FDA1427 ([redacted]); FDA1438 ([redacted]); FDA1473 ([redacted]); FDA988 [redacted]; FDA984–87 ([redacted]).

The record also contains survey data, *see, e.g.*, FDA708–09; FDA724–34; FDA970–72; FDA977–78, press articles, *see, e.g.*, FDA794; FDA799, and letters, *see, e.g.*, FDA631; FDA817, all confirming a shortage. There is simply too much of this information to dismiss out of hand, as FDA irrationally did.

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The Court has already ruled that Plaintiffs' arguments on the merits "failed." ECF No. 100 at 6. Plaintiffs are respectful of the Court's time and heavy case load and do not seek to further burden the Court by presenting it with arguments it has already found unpersuasive. For the Court to determine that further proceedings on the merits would have value—where all sides have already fully aired their positions—would have to reflect a judgment that the outcome at judgment will likely be different. If the Court determines that, then the proper course of action would be to promptly reconsider its preliminary-injunction order, issue an injunction now to preserve the status quo for the weeks leading to final judgment, and schedule expedited summary judgment proceedings. The Court has power to "revise" an interlocutory order and "grant an injunction" notwithstanding a pending interlocutory appeal. Fed. R. Civ. P. 54(b), 62(d). Aside from the jointly requested relief of converting the Court's preliminary-injunction order into a final judgment, that is the only path that would serve the interests of "the significant number of people who will be affected by this matter." ECF No. 109 at 2.

Respectfully submitted,

Dated: March 25, 2025

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